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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,729	09/15/2003	Yitzhak Berger	1837-100US	1518
25881	7590	02/17/2006	EXAMINER	
EPSTEIN DRANGEL BAZERMAN & JAMES, LLP 60 EAST 42ND STREET SUITE 820 NEW YORK, NY 10165			SZMAL, BRIAN SCOTT	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/662,729	BERGER ET AL.	
	Examiner	Art Unit	
	Brian Szmaj	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Claim Objections

1. Claim 19 is objected to because of the following informalities: In line 2, "the stored electrical signals" lacks antecedent basis. Appropriate correction is required.
2. Claim 37 is objected to because of the following informalities: In line 17, "the electrical signals" lack antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 16-32 and 34-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Garfield et al (5,776,073).

Garfield et al disclose a method and apparatus for analyzing electrical activity from surface measurements and further disclose applying measurement electrodes to the abdomen of the patient; acquiring electrical signals from the electrodes to record action potentials; amplifying the electrical signals; analyzing the electrical signals to diagnose the bladder condition; acquiring electrical signals comprises acquiring electrical signals from the electrodes in the areas of the body selected from the group consisting of the abdomen region, the supra pubic region and the perineal region; acquiring electrical signals comprises acquiring analog electrical signals from the electrodes representing action potentials, at a sampling frequency of between about 0.001 Hz and 5 MHz;

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bladder activity is characterized by analyzing the stored electrical signals of at least one burst of action potentials; characterizing bladder activity comprises determining at least one of the parameters of the action potentials selected from the group of frequency duration, mean frequency, amplitude, power density spectrum of the bursts and the frequency, duration, and amplitude of the at least one burst of action potentials; characterizing bladder activity comprises determining at least one of the parameters of the at least one burst selected from the group of frequency, duration, mean frequency, amplitude, power density spectrum, and amplitude; characterizing bladder activity comprises determining fast wavelet transform characteristics of the frequency components of the electrical signals; characterizing bladder activity comprises determining joint time-frequency characteristics of said frequency components of bursts of action potentials within the electrical signals; characterizing bladder activity comprises: determining the mean frequency of the burst of action potentials; determining the starting frequency of the burst of action potentials; and determining the ending frequency of the burst of action potentials; characterizing bladder activity comprises determining the rate of rise of amplitude of the at least one burst of action potentials; and determining the rate of fall of amplitude of the at least one burst of action potentials; characterizing bladder activity comprises examining one or more trends in the electrical signals or parameters representing the electrical signals over time as indicated by the determined parameters; displaying the one or more trends in bladder activity; predicting future bladder activity based on one or more trends in bladder activity; predicting future bladder activity comprises the steps of: comparing the one or

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more trends in bladder activity of a patient with trend data collected from other patients in order to identify matching trends; and predicting future bladder activity for a patient under examination based on the trend behavior shown in the matching trends; the predicting is performed by a programmed computer functioning as an expert system; one or more electrodes capable of measuring action potentials recorded from the surface of a studied a patient; an amplifier electrically coupled to said electrode to receive and amplify a signal indicative of action potentials measured by said electrode; an analog to digital converter coupled to the amplifier for digitizing the signals from the amplifier; a memory comprising sufficient storage capacity to store data resulting from a sampling of the action potentials, said memory coupled to receive a digital input from the analog to digital converter; a filtering device capable of segregating and identifying electrical signals; and a programmed computer, the computer programmed to analyze the frequency, duration, amplitude, and power density spectrum of action potentials, the programmed computer further being capable of characterizing bladder activity based upon the analysis; a data transmitter to receive the amplified signal from the amplifier and to transmit the signal to a location remote from the electrode; a data receiver to receive the transmitted signal in the location remote from the electrode; the transmission is analog; an analog to digital converter coupled to the amplifier and wherein the transmitter is a digital transmitter; the transmission type is selected from the group consisting of infra red (IR), acoustic, radio (wireless), wire, cable, and optical fiber; and the amplifier and transmitter are portable. See Column 3, lines 66-67; Column 4, lines 1-21 and 64-67; Column 5, lines 1-18; Column 6, lines 20-45; Column 9, lines

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21-34; Column 10, lines 25-37 and 56-64; Column 11, lines 62-66; Column 12, lines 15-16; Column 15, lines 26-60; Column 16, lines 23-30; and Column 22, lines 49-63.

Even though Garfield et al primarily discloses the use of the device for measuring and determining uterine contractions, the device is clearly discloses as being used for measuring bladder function in Column 4, line 1. Due to that disclosure, the electrodes are inherently placed in the lower abdominal region for measuring bladder activity.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al (5,776,073) as applied to claim 31 above, and further in view of Forgione et al (4,088,125).

Garfield et al however fail to disclose an audio amplifier and a speaker to make analog sounds indicative of action potentials measured by the electrode.

Forgione et al disclose a method and apparatus for monitoring skin potential response and further disclose an audio amplifier and a speaker to make analog sounds indicative of action potentials measured by the electrode. See Column 3, lines 52-58.

Since both Garfield et al and Forgione et al disclose means for obtaining EMG signals and providing an output, it would have been obvious to one of ordinary skill in the art at

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the time the invention was made to modify the device of Garfield et al to include the use of an audio amplifier and a speaker for the measured signals, as per the teachings of Forgione et al, since it would provide another means of output for the physician in addition to the visual display.

Allowable Subject Matter

7. The following is a statement of reasons for the indication of allowable subject matter: Claims 1-15 contain allowable subject matter, in particular, converting the VISEMG waveforms to non-invasive urodynamic graphs, as claimed in Claim 1; and a plurality of input amplifiers for receiving electrical signals from VISEMG surface electrodes, each amplifier including at least one filter coupled to the amplifier for filtering each VISEMG signal, and conversion software for converting VISEMG waveforms to non-invasive urodynamic graphs, as claimed in Claim 7.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

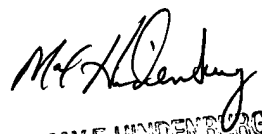
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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